Site visit inspection report on compliance with HTA licensing standards
Inspection date: **09-11 March 2020**

London Bridge Hospital

HTA licensing number 11069

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

Licensed activities

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'SLA' = Service Level Agreement; the establishment is licensed for this activity, but another licensed establishment carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub **London Bridge Hospital**	E*/SLA			E			
Satellite **The Princess Grace Hospital**	E			E			

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Satellite **The Wellington Hospital**	E*			E			
Satellite **The Harley Street Clinic**	E						
Satellite **Hospital Corporation of America (HCA) Laboratories - Shropshire House**			E				

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	Authorised*		Authorised*				

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone				Authorised			
Musculoskeletal, Tendon & Ligament; Tendons				Authorised			
Musculoskeletal, Tendon & Ligament; Ligaments				Authorised			
Skin; Skin				Authorised*			
Membrane, Fascia Lata; Fascia Lata				Authorised			
Neuronal; Nerves				Authorised*			
Musculoskeletal, Cartilage; Cartilage (ATMP)	Authorised		Authorised				
Other; Tumour (ATMP)	Authorised		Authorised				

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that London Bridge Hospital (the establishment) had met the majority of the HTA's standards, nine minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	There were several examples where documented procedures did not reflect the current practices described by the staff or observed during visual inspections. These included, but were not limited to: • the temperature alarm limits for the -80ºC freezers; • the reagents used to clean the freezers; • procedures for transferring tissues to contingency freezers; • procedures for the use and retention of human tissue tracking forms and delivery notes; and • the entry of information from receipted tissue products into the electronic tissue register, without delay.	**Minor**

d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.	There was an inconsistent approach to document control at the establishment. The establishment's document control policy sets a review period of three years, except for new procedures which must be reviewed within 12 months of authorisation. The review periods assigned to several policies that were in use at the time of the inspection were not aligned with this requirement. Several out of date forms for recording freezer temperatures and the weight of the carbon dioxide cylinder were in use at one of the satellites.	**Minor**
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.	Currently, there is no written agreement in place with the laboratory carrying out confirmatory syphilis testing for the establishment.	**Minor**
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.	The establishment sends positive blood samples to third party laboratories for confirmatory serology testing. However, the agreements do not specify the responsibilities of the third parties and do not meet the requirements set out in Directions 002/2018.	**Minor**
GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	An audit was conducted in October 2019 by the current DI. Whilst the audit was performed against applicable HTA standards, it was not carried out in an independent manner because the DI has the responsibility of overseeing the establishment's licensable activities.	**Minor**

GQ4 There is a systematic and planned approach to the management of records.		
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.	Temperature records for tissue storage freezers are not regularly audited. Several excursions from the establishment's required temperature ranges were observed during the review of freezer temperature records at two of the satellites. These excursions were not detected at the time they occurred and there was no subsequent review process. As a result, there was no documented explanation of what happened and no action was taken to establish the impact, if any, these excursions had on the quality and safety of the tissues stored in the freezers at the time. During a traceability audit at The Wellington Hospital (TWH), it was identified that the information for two tissue products had been transposed onto the incorrect human tissue tracking forms.	**Minor**
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.	The establishment is currently participating in a clinical trial involving the procurement of tumour tissue that is sent to the Netherlands to be manufactured into an Advanced Therapy Medicinal Product (ATMP). The testing of the two donors from whom tissue has been procured to date did not include all the mandatory serology markers stipulated by Directions 002/2018.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes.	The establishment has a range of risk assessments; however, these do not cover the scope of the licensable activities carried out under the licence. In addition to this, some of the establishment's risk assessments were not dated, and it was not possible to determine when they were due to be reviewed.	**Minor**
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	A risk assessment of the premises has been conducted at Shropshire House (SH); however, this was outside of the annual review period as it was carried out in June 2018. The establishment was unable to provide copies of premises risk assessments for the hub and other three satellite sites.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	-	The HTA has identified areas which would benefit from better oversight by the DI. The DI is advised to explore additional ways to increase his familiarity with work carried out at each site to ensure that he has and maintains

		appropriate oversight of licensable activities. The DI is encouraged to maintain good lines of communication with the PDs in order to stay up to date with the latest activities at each of the five sites.
2.	-	The establishment regularly orders a number of tissue products from suppliers for end use which are not stored for more than 48 hours. The DI is advised to implement a policy for the addition of new tissues types and/or new licensable activities which includes the storage of tissue products beyond 48 hours to reinforce standard condition 14 of the establishment's HTA human application licence. The policy should include the process to notify the DI of any proposed new licensable activities; the DI must then notify the HTA for formal authorisation before commencing any new activities.
3.	GQ2b, GQ4c	There was an inconsistent approach to internal audits across sites; some sites had carried out audits whilst other sites had not. The DI is advised to extend the internal audits to the hub and all the satellites and ensure that written records are indelible and complete. The DI is also advised to ensure that findings and corrective actions are documented with set deadlines, and to regularly share the lessons learned to all the relevant staff working under the licence.
4.	GQ4a, GQ8a	It was identified at one of the satellites that the human tissue tracking forms were being updated electronically and reprinted with additional information; the original forms were subsequently discarded. The DI is advised to assess the risk of errors being introduced when transposing information, and the risk of discarding tracking forms which are used to record the original cold chain information.
5.	GQ3e	The DI is advised to define the frequency of refresher training for all staff undertaking licensable activities. This will help to ensure that all staff are familiar with current procedures, and that staff who were unable to attend a training session are identified so that their training can be completed as soon as practicably possible.
6.	GQ4h, GQ4i, GQ4m	The DI is advised to update all documents that specify data retention periods to clearly reflect the regulatory requirements, which are as follows:

		• raw data which are critical to the quality and safety of tissues and cells must be kept for 10 years after the use, expiry or disposal of the tissues and/or cells; and • the minimum data to ensure traceability from donor to recipient must be kept for 30 years after the use, expiry or disposal of the tissues and/or cells.
7.	GQ6d	It was identified that a number of tissue products were received from tissue suppliers without the Single European Code (SEC) on the product or within the accompanying documentation. The DI is advised to put systems in place that enable the SEC to be linked to the end user.
8.	GQ7a	The establishment uses an electronic system to report and record adverse incidents. Some of the incident records reviewed during the inspection did not contain enough detail to fully capture the corrective and preventative actions put in place to manage the incident and prevent recurrence. The DI is advised to implement a process that ensures each incident is documented as clearly and completely as possible, and to ensure any newly identified areas of risk are formally assessed.
9.	GQ8c	HCA Laboratories at SH has prepared a detailed risk assessment of the serology laboratory processes since 2019. The DI is advised to complete this risk assessment and make this available to staff working under the licence as soon as possible so that staff are aware of the risks and mitigation steps associated with the licensable activities.
10.	PFE3d	The electronic human tissue register automatically calculates a six-month expiry date from the date of receipt for tissue products stored at -40ºC. However, in some circumstances, the tissue supplier assigns their own six-month expiry based on the day of packing, which is typically the day before receipt. In such cases, the establishment's assigned expiry date exceeds the supplier's assigned expiry date by one day. The DI is advised to update the tissue register's algorithm for calculating the expiry date for tissue products to ensure that it cannot exceed the supplier's assigned expiry date.

Background

London Bridge Hospital (LBH) has been licensed by the HTA since December 2006. This was the seventh site visit inspection of the establishment; the most recent previous inspection took place in March 2018.

Since the previous inspection, there have been a number of significant changes to the licence arrangements and the activities carried out under the licence. There have been two changes of the DI, the addition of new activities and tissue types, and the revocation of a satellite testing laboratory at Wimpole Street.

LBH is the main hub and one of five premises where HTA-licensable activities take place. The hub stores bone, tendons, and ligaments in a -80ºC freezer. The hub also stores acellular bone and demineralised bone matrix (DBM) putty at ambient temperature, LBH is authorised for storage of skin tissue but is not currently carrying out this activity.

The Princess Grace Hospital (PGH) stores bone, tendons and ligaments in a -80ºC freezer. This satellite has recently resumed procurement of cartilage tissue which is sent to Germany as a starting material for the manufacture of an ATMP, however this activity was not reviewed on this inspection. PGH also stores acellular bone such as DBM putty and cancellous bone chips at ambient temperature.

TWH is authorised to store tendons and ligaments, which would normally be stored in the -80ºC freezer. At the time of the inspection TWH was not storing any tissues in the -80ºC freezer because the freezer was out of use and awaiting a service. Fascia Lata is stored at ambient temperature alongside acellular bone products such as DBM putty. TWH is also authorised to store neuronal tissue but is not currently doing so.

Since the last inspection, the establishment has varied the licence to undertake the procurement of tumour tissue at The Harley Street Clinic (HSC). Tissue is procured as the starting material for one of two different ATMP’s, one of which is manufactured at a site in London and the other at a site in the Netherlands. Donor blood samples for the ATMP manufactured in London are tested for mandatory serology markers under the authority of the manufacturer’s HTA licence, whilst the serology samples for the ATMP manufactured in the Netherlands are sent to the HCA Laboratories at SH for testing under the authority of the establishment’s HTA licence. The preparation of media for the tumour tissue sent to the Netherlands is carried out at the Sarah Cannon Research Institute by trained staff.

LBH, PGH, TWH and HSC also order a number of tissue products from suppliers for end use which are not stored for more than 48 hours; these include tissues such as cartilage, meniscus, vessels, amniotic membrane, ocular tissue and heart valves. If the tissues are not used, they may be returned to the supplier, provided that the box remains unopened and the manufacturer's stipulated timeframe has not been exceeded.

The HCA laboratories at SH is accredited by the United Kingdom Accreditation Service (UKAS). The establishment may send blood samples that test positive for mandatory serology markers to four different laboratories for confirmatory testing. Three laboratories are located in the UK and one is located in France. There are third party agreements in place with three of these testing laboratories (*see shortfall, under GQ1p)*.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

Standards covered at this inspection are listed in Appendix 3. Any standards that were not applicable to the establishment have been deleted from this table. Any standards that were applicable, but were not covered during the inspection or audit, have been highlighted in grey.

Review of governance documentation

The inspection included a review of documentation relevant to the establishment's licensable activities. This included policies and procedural documents, risk assessments, internal and independent audits, staff training records, equipment maintenance records, reported incidents and adverse events, governance meeting minutes, agreements with third parties and temperature monitoring records of freezers and storage areas.

Visual inspection

The visual inspection took place at the hub and three of the satellites. The inspection team inspected the freezers and cabinets where tissues are stored at the hub, PGH and TWH. The HCA Laboratories at SH was inspected which included the sample receipt area, sample processing areas,

cold room where the kits are stored, and the freezer where the serology blood samples are stored after testing. The inspection team also visited HSC where the records of tumour procurement were reviewed.

Audit of records

Traceability audits were carried out at the hub and each of the four satellites. The audits included:

- six tissue products cross-checked against the tissue register at the hub; three tissue products were used for human application and three tissue products were in storage at the time of inspection. No discrepancies were noted;
- eight tissue products cross-checked against the tissue register at PGH; five tissue products were used for human application, two tissue products were disposed, and one tissue product remained in storage at the time of inspection. No discrepancies were noted;
- nine tissue products cross-checked against the tissue register at TWH; seven tissue products were used for human application, one tissue product was disposed, and one tissue product was returned to the supplier. Discrepancies were noted in the paper copies of the human tissue tracking form where a tissue product was not booked into the tissue register on receipt, in this case there was no record of the tissue between receipt and disposal on the tissue register, therefore it was not possible to determine where the tissue was stored during this time leading to a risk of loss of traceability (*in addition to this discrepancy, see shortfall under GQ4b*);
- tumour tissue procurement records from two patient's at HSC. The tumour tissue was sent to a manufacturing site in London to create a tumour vaccine; the patient information sheets, consent records, collection kit dispatch notes, blood collection forms and tissue collection forms were reviewed. No discrepancies were noted; and
- tumour tissue procurement records from two patient's at HSC for a phase 2 clinical trial. This tissue was sent to a manufacturing site in the Netherlands for ATMP manufacture; the following records were reviewed - patient information, patient consent, media preparation, procurement, labelling, packing, courier, site initiation and staff training. The serology results from these two donors were traced back to the electronic systems at HCA Laboratories at SH. It was noted for both donors that not all the mandatory serology testing had been requested or performed (*see shortfall, under GQ5b).*

Meetings with establishment staff

Discussions were held with the DI, the PDs and staff carrying out licensable activities at the hub and four satellites. The inspection team met with two of the PDs at the hub, a Lead Theatre Practitioner and Chief Clinical Perfusionist, three of the PDs at PGH, a Lead Theatre Practitioner, Senior Theatre Practitioner and Theatre Coordinator, two of the PDs at TWH, a Theatre Coordinator and Theatre Manager, two of the PDs at HSC, the Patient Safety Manager Surgical Services and the Head of Theatres and Strategy, and one of the PDs at SH who is the Risk and Compliance

Manager. In addition to this, discussions were held with the Section Head in Serology and the Lead Quality Manager at SH, the Quality Superintendent at HSC, and the staff at the Sarah Cannon Research Institute which included the Clinical Quality Assurance Manager and the Principal Investigator who is also the Director of Drug Development.

Report sent to DI for factual accuracy: 08 April 2020

Report returned from DI: 01 May 2020

Final report issued: 06 May 2020

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007, or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of ‘major’ shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the

issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA Standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Consent
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.

d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.

i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.

b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed,

stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.

f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.

c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.

d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.